



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 6, 2023

Casey Pehrson
Authorized Agent for A&P Inphatec, LLC
Exponent, Inc.
1150 Connecticut Ave. NW
Suite 1100
Washington, DC 20036

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – To
Replace All TM Symbols with ® Symbols
Product Name: XylPhi-PD
EPA Registration Number: 93909-1
EPA Receipt Date: 01/25/2023
Action Case Number: 00427531

Dear Ms. Pehrson:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to EPA’s Office of Enforcement and Compliance Assurance.

If you have any questions, please contact Monica Thapa by phone at (202) 566-1543 or via email at thapa.monica@epa.gov.

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Action Case No. 00427531

Sincerely,

CODY

KENDRICK

Digitally signed by
CODY KENDRICK

Date: 2023.02.06
08:26:06 -08'00'

Cody Kendrick, Senior Regulatory Advisor
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure

{Note: Text in curly brackets indicates optional text.}
[Note: Text in square brackets is a note to the reviewer.]

NOTIFICATION

93909-1

XylPhi-PD™[®]

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/06/2023

Bactericide for use in grapevines

{Biological control for {reduction}{decrease} of Pierce’s Disease in grapevines}

{Biologically-based {reduction}{decrease} of Pierce’s Disease in grapevines}

{Preventative reduction of the onset of Pierce’s Disease in grapevines}

{Preventative and curative {reduction of}{decrease in} the symptoms of Pierce’s Disease in grapevines}

{Bacteriophage designed to selectively target and reduce the bacteria in grapevines that cause Pierce’s Disease}

{For Use in Organic Production}



{Listed by Organic Materials Review Institute (OMRI)}

Active Ingredient:

Bacteriophage active against *Xylella fastidiosa** 0.00013%

Other Ingredients:..... 99.99987%

Total:..... 100.00000%

*Contains a minimum of 5 x 10⁹ plaque forming units (PFU) per milliliter of product

KEEP OUT OF REACH OF CHILDREN

{See {insert}{booklet} for {Precautionary Statements} {and} {Directions for Use}.}

[Note: The Signal Word (per 40 CFR 156.64) and First Aid Box (per 40 CFR 156.68) are not required because the product is classified as Toxicity Category IV for all routes of exposure and is negative for dermal sensitization.]

HOTLINE NUMBER

For general information on this product, call 1-650 337-0350 during normal business hours, 8 am to 5 pm (Pacific Time). Contact 1-800-222-1222 for emergency medical treatment information.

EPA Reg. No. 93909-1

EPA Est. No. XXXX-XX-X

Produced For:
A&P Inphatec, LLC
1060 E Meadow Circle
Palo Alto, CA 94303

Net Contents: XXX
{Batch}{Lot} No.: XXX

XylPhi-PD™; EPA Reg.. No. 93909-1
MASTER LABEL – ~~December 4, 2020~~
January 24, 2023

{Note: Text in curly brackets indicates optional text.}
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PRECAUTIONARY STATEMENTS

[Note: The Hazards to Humans and Domestic Animals section is not required per 40 CFR 156.70 because product is classified as Toxicity Category IV for all routes of exposure and is negative for dermal sensitization.]

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS:

Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PRODUCT INFORMATION

{Bacteriophage selectively target and attack bacteria. Bacteriophage typically target specific ranges of bacteria. Once the phage come in contact with their targeted bacteria, they enter and

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destroy their targets, all while they are generating more phage that go on to attack more targeted bacteria.}

Pierce's Disease in grapevines is caused by the bacterium called *Xylella fastidiosa*. XylPhi-PDTM is comprised of bacteriophage that are designed to attack this bacterium. XylPhi-PDTM uses the specific nature of these phage to find and eliminate the bacteria within grapevines that the phage contact, decreasing the {amount}{level}{number} of *Xylella fastidiosa* that can cause the symptoms of Pierce's Disease in the grapevines.

XylPhi-PDTM can be used as a preventative and curative solution for {reducing}{decreasing}{lessening}{diminishing} the symptoms of Pierce's Disease in grapevines by targeting the bacterium that causes Pierce's Disease, *Xylella fastidiosa*.

XylPhi-PDTM can be applied as a preventative to protect growing vines, as a curative when disease symptoms become visible, or when conditions may lead to disease pressure. Apply XylPhi-PDTM with the specified injection device (see Application Instructions).

APPLICATION INSTRUCTIONS

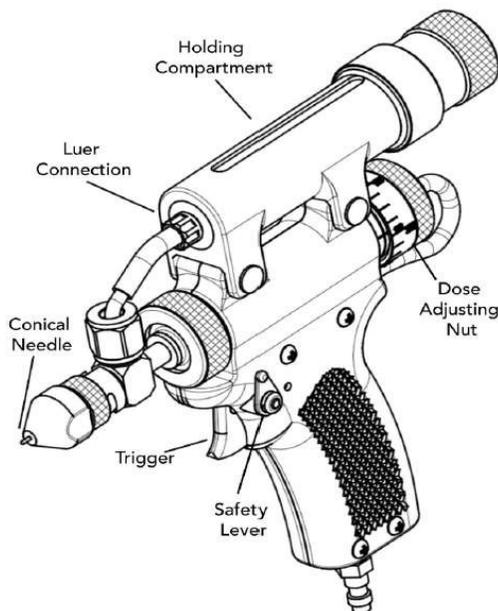
Preparation of Plants for Application: Inject XylPhi-PDTM when uptake of water or product into the xylem vessels, the plant's vascular system, is optimal. Do not inject XylPhi-PDTM when plants' xylem is saturated or shortly after heavy rainfall or irrigation.

Application by Injection: XylPhi-PDTM applications are made by injection of the product into the vascular system of grapevines. Applications are made directly into the active xylem tissue of the plant. This section describes the following: the injection locations on the vines; the injection device to be used; the appropriate procedures to be followed to ensure optimal effectiveness of XylPhi-PDTM; and the application process.

Injection Device: Applications of XylPhi-PDTM are to be made with a pressurized injection device that can deliver the application volumes described in this section, utilizing the needle gauge and length that enables consistent and effective delivery into the vascular systems of the treated plants.

[Note: Representative picture of injection device, with labels indicating the key components of the injection device, will be inserted here. An example of this graphic is provided in the figure below.]

{Note: Text in curly brackets indicates optional text.}
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An injection device such as a Pulse *Xyleject*TM Injection System (Pulse Biotech, LLC; Lenexa, KS), or an equivalent, as configured to accept a needle using an 18- or 20-gauge conical needle is required. A 20-gauge needle is typically only needed when injecting into a newly planted vine or within newly grown suckers of severely affected plants. For the remainder of applications, use an 18-gauge needle. The injection device must be able to inject XylPhi-PDTM into the vine using pressurized injections at a needle penetration depth between 0.08 in. (2 mm) and 0.39 in. (10 mm), depending on the diameter and age of the plant tissue as detailed in this section.

Priming Holding Compartment and Injection Device: Introduce XylPhi-PDTM into the injection device's holding compartment as specified by the manufacturer. The entire capacity of the holding compartment does not need to be filled with XylPhi-PDTM if the anticipated number of injections is limited. In such cases, the amount of XylPhi-PDTM added to the holding compartment may match the number of injections to be performed with the device, with addition of extra liquid volume as necessary to fill the injection device fluid path and prime the injection device.

Prime Holding Compartment: Once XylPhi-PDTM is within the injection device's holding compartment, air must be removed from the holding compartment. Position the holding compartment's outlet port upward, and manually press the holding compartment plunger to expel excess air from the holding compartment until all air pockets in the holding compartment are filled with XylPhi-PDTM. It is important to remove all air from the holding compartment before installing the holding compartment on the injection device.

Prime Injection Device: After the primed holding compartment is installed on the injection device following the manufacturer's directions, the injection device must be primed. Set the injection device dose volume to the maximum dose volume. Place the injection

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device upward (needle pointed upward) and compress the trigger or actuate the injection device several times until a steady stream of liquid is expelled out of the needle. Once a steady stream of liquid is expelled, hold the injection device in its normal position. Select the desired injection device dose volume setting. The injection device is now ready to inject XylPhi-PD™ into the vines.

Injection Site Locations: Select the application locations for XylPhi-PD™ based on the age of the plant, pruning style, and the training system utilized for the plant. Inject XylPhi-PD™ into the active xylem vascular tissue, and only inject XylPhi-PD™ above ground. An overview of the appropriate locations for injections into grapevines for different types of grapevine training and age is provided in the first table below. Apply 2 or 3 injections in the arms based on the vine pruning style. Two injections can be applied at the crown of the trunk in mature vines, where pruning and branching have occurred. It is most critical, however, to apply XylPhi-PD™ in the cordons and spurs, per the details on pruning style, where there are active xylem vessels.

Cordon Training: Apply 1 injection in each cordon above the bifurcation but within the cordon arm and before the first spur.

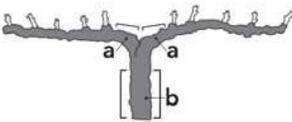
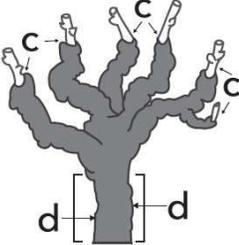
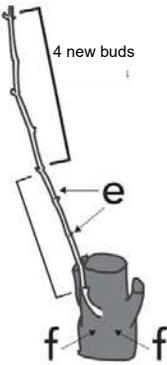
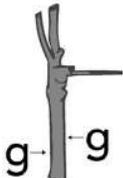
Alternative Training Methods (e.g., goblet or head, vertical cordon, 6-arm Kniffen or similar): Apply 1 injection into each 1-year spur at each arm. It is ideal to apply an injection at each arm; however, at a minimum, inject up to 3 arms per vine. If all arms are not covered in initial application, consider application into different arms upon subsequent treatments.

For young, recently planted, or radically pruned vines, apply 1 to 2 injections into the crown of the trunk approximately 180° apart.

Injection Depth and Pressure: Inject XylPhi-PD™ at a needle penetration depth between 0.08 in. (2 mm) and 0.39 in. (10 mm), depending on the diameter and age of the plant tissue. Inject XylPhi-PD™ using the injection device's required pressure settings. After inserting the needle into the plant, hold the injection device firmly against the plant and depress the device actuator to deliver the injection. The needle penetration depth is controlled by changing the needle retention nut. A set of needle retention nuts is included with the device. The different needle retention nuts allow for varying lengths of the needle to be exposed beyond the needle retention nut. For deeper injections, select a needle retention nut that exposes a longer portion of the needle beyond the needle retention nut. For shallow injections, select a needle retention nut that exposes a shorter portion of the needle beyond the needle retention nut.

Application Locations, Frequency, Timing and Rates: XylPhi-PD™ applications are made by direct injection into grapevines, as summarized in the following tables:

{Note: Text in curly brackets indicates optional text.}
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Types of Grapevine Training	Diagrams of Grapevines	Number of Applications Needle Size Injection Locations Injection Volume
Uni-, Bi-, and Quadri-Lateral Cordon Vines; Cane-Pruned Vines		<ul style="list-style-type: none"> • Make 3 applications of XylPhi-PDTM per year Use an 18-gauge needle • For each application, apply a minimum of 1 injection into each cordon just after the T (a) plus 1 - 2 injections into the trunk (b) • Apply 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PDTM per injection
Head-Trained Vines		<ul style="list-style-type: none"> • Make 3 applications of XylPhi-PDTM per year Use an 18-gauge needle • For each application, apply 1 injection into each arm at location of 1-year-old spur with a minimum of 3 arms (c) plus 2 injections at trunk 180° from each other (d) • Apply 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PDTM per injection
Cut Down, Retrained Vines		<p>For New Shoots:</p> <ul style="list-style-type: none"> • Make 3 applications of XylPhi-PDTM per year Use a 20-gauge needle • For each application, apply 1 - 2 injections into each shoot event (e) • Apply 0.0014 fl. oz. (40 µL) of XylPhi-PDTM per injection <p>For the Trunk:</p> <ul style="list-style-type: none"> • Make 2 applications of XylPhi-PDTM per year • Use an 18-gauge needle • For each application, apply 2 injections into the trunk on both sides and below new shoot growth (f) • Apply 0.0027 fl. oz. (80 µL) of XylPhi-PDTM per injection
Replants; New Vines		<ul style="list-style-type: none"> • Make 2 applications of XylPhi-PDTM per year Use a 20-gauge needle • For each application, apply 2 - 3 injections into shoot at 180° from each other (g) • Apply 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PDTM per injection

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Rate	Timing	Frequency
<p>Use 0.0014 fl. oz. (40 µL) – 0.0027 fl. oz. (80 µL) of XylPhi-PDTM per injection.</p> <p>For mature plants, apply XylPhi-PDTM as detailed above.</p> <p>For newly planted, young vines, or vines that have been trimmed to 2 in. (5 cm) – 6 in. (15 cm) above the ground, apply XylPhi-PDTM as detailed above.</p>	<p><u>Primary Injection:</u> Generally 6 - 8 weeks (or earlier in heavy disease pressure) after new flush from dormancy.</p> <p><u>Secondary Injection:</u> 4 - 6 weeks after primary injection.</p> <p><u>Tertiary Injection:</u> As appropriate, 4 - 6 weeks after second injection.</p>	<p>Conduct 2 - 3 treatments per growing season depending on disease pressure.</p>

Cleaning Injection Device: Upon completion of applications or at the end of an application day, clean the injection device in accordance with the injection device instructions. These instructions will include cleaning the injection device to ensure that XylPhi-PDTM residue is thoroughly removed from the injection device, that the injection device is free of plant debris and that the injection device is stored appropriately in between uses.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in original container. Store this product in a dry area at either room temperature or under refrigerated conditions (36 – 80°F, 2 – 27°C), away from direct sunlight and extreme heat. Inappropriate storage may cause degradation of the product and that would decrease product efficacy.

Pesticide Disposal: To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

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IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as, including, but not limited to, the extent of the existing symptoms of Pierce's Disease in the treated grapevines, the pressure of further introduction of disease by vectors such as sharpshooters, the overall health of the grapevines, weather conditions, presence of other materials and the challenges of the method of application, all of which are beyond the control of A&P Inphatec, LLC. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, A&P Inphatec, LLC makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of A&P Inphatec, LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, A&P Inphatec, LLC disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at A&P Inphatec, LLC's election, the replacement of product.